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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,739	09/11/1998	MARY M. BENDIG	15270-001430	9068

7590 06/08/2004

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EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,739

Applicant(s)

BENDIG ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-27 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment, filed 2/26/04, has been entered.
Claim 1 has been canceled. Claims 2-17 have been canceled previously.
Claims 18 and 19 have been amended.

Claims 18-27 as it reads on the election of rheumatoid arthritis are under consideration in the instant application.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 2/26/04.
The rejections of record can be found in the previous Office Actions.

3. Again, it is noted that a number of pages in the specifications have faint or missing words.

Applicant may consider providing a substitute specification or may consider discussing the issue with the examiner in order to correct the deficiencies in the specification.

If a substitute specification is submitted to correct the numerous entries to be amended in the specification, then the substitute specification filed must be accompanied by a statement that it contains no new matter. Such statement must be a verified statement if made by a person not registered to practice before the Office.

As noted by applicant's amendment, filed 7/14/03 and 2/26/04; this objection will be held in abeyance until there is an indication of allowable subject matter.

4. Given the cancellation of claim 1, particularly the claimed recitation of methods of using the humanized 21.6 antibody for "manufacturing a medicament for treating rheumatoid arthritis"; the priority of the instant claims appear to be the 11/21/95 priority filing date, which is the filing date of USN 08/561,521, now U.S. Patent No. 5,840,299.
5. Given the cancellation of claim1, particularly the claimed recitation of methods of using the humanized 21.6 antibody for "manufacturing a medicament for treating rheumatoid arthritis"; the previous objection to the specification as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l) has been withdrawn.
6. Given the cancellation of claim1, particularly the claimed recitation of methods of using the humanized 21.6 antibody for "manufacturing a medicament for treating rheumatoid arthritis"; the previous rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.
7. Claims 18-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wayner et al. (U.S. Patent No. 5,730,978) in view of Bendig et al. (WO 95/19790;IDS, #10) essentially for the reasons of record set forth in the previous Office Actions.

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Applicant's arguments, filed 2/26/04, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Applicant traverses this rejection for the reasons previously set forth in the Amendment and Reply dated 10/17/01; however, it is unclear what communication is being relied upon, given that no paper in this file application is dated 10/17/01.

Applicant's comments on the criteria of obviousness are acknowledged.

Applicant again asserts that the references fail to provide the requisite suggestion or motivation to either modify and/or combine the reference teachings to arrive at the claimed invention. Applicant asserts that the prior art fails to teach or suggest the treatment of rheumatoid arthritis as well as the use of the particular humanized 21.6 antibody to treat rheumatoid arthritis.

Again, applicant submit that multiple sclerosis and rheumatoid arthritis were considered to be two completely different disease with divergent etiologies and symptoms.

As previously noted, while the etiologies of the autoimmune diseases and experimental models of autoimmune diseases do have different etiologies, the prior art, as well as applicant's disclosure recognized that the ordinary artisan could target inflammatory mediators (e.g. cells) associated with these conditions in order to treat these conditions with an expectation of success at the time the invention was made. Again, it is noted that Wayner et al. does teach targeting a number of inflammatory or autoimmune conditions, including rheumatoid arthritis. In addition, given that the teachings of Bendig et al. to treat the highly difficult case of multiple sclerosis, the ordinary artisan would have had a reasonable expectation of success in treating other autoimmune conditions such as rheumatoid arthritis.

Also, it is noted that Example 9 of the instant specification discloses the efficacy of the humanized 21.6 antibody in the prophylactic and therapeutic treatment of EAE in an animal model simulating multiple sclerosis in humans. Therefore, applicant has relied upon experimental models of treating EAE to support the ability of the humanized 21.6 antibody to treat autoimmune diseases encompassing rheumatoid arthritis as well as multiple sclerosis (also, see Section VII, Methods of Treatment on pages 25-31 of the instant specification).

In addition, the Background of the Invention of the instant specification is consistent with the prior art that $\alpha 4$ is a therapeutic target to treat pathologic inflammation by inhibiting over-responsive leukocytes. It is noted that Wayner et al. discloses a number of diseases including autoimmune diseases such as rheumatoid arthritis and multiple sclerosis with a common mode of action to Bendig et al. as well as the instant application.

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Again, applicant has not addressed the clear teachings of the prior art drawn to inhibiting deleterious inflammation by targeting leukocytes with $\alpha 4$ -specific antibodies to treat a number of inflammatory and autoimmune conditions, which is consistent with the same mode of action relied upon by the instant disclosure.

Again, applicant fails to address the clear teachings of the prior art of both Wayner et al. and Bendig et al. of inhibiting the inflammatory responses in autoimmune responses with $\alpha 4$ -specific antibodies, including rheumatoid arthritis and the particular humanized 21.6 antibody of the claimed invention

A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See In re Gurley, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

Here in contrast to applicant's assertions of teaching away by the prior art provide by applicant, there is no discouragement nor skepticism in the prior art employed in the rejection under 35 USC 103 itself for inhibiting the inflammatory responses in autoimmune responses with $\alpha 4$ -specific antibodies, including rheumatoid arthritis and the particular humanized 21.6 antibody of the claimed invention

In response to applicant's arguments that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992). In this case the teachings of both Wayner et al. and Bendig et al. teach inhibiting the inflammatory responses in autoimmune responses with $\alpha 4$ -specific antibodies, including rheumatoid arthritis and the particular humanized 21.6 antibody of the claimed invention and the teachings of both Wayner et al. and Bendig et al. teach and claim success in treating inflammatory conditions to solve the same or nearly the same problems of pathologic inflammation in inflammatory and autoimmune conditions by targeting leukocytes with $\alpha 4$ -specific antibodies would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art.

The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

Applicant's arguments are not found persuasive.

8. No claim is allowed.

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9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
May 24, 2004